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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|-------------------------|---------------------|------------------|
| 10/049,497 | 02/13/2002 | Edel Bernadette O'Toole | CM2140 | 7650 |
| 27752 | 7590 | 03/17/2004 | EXAMINER | |
| CHANNAVAJJALA, LAKSHMI SARADA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1615 | | | | |
| DATE MAILED: 03/17/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/049,497 | O'TOOLE ET AL. |
| | Examiner | Art Unit |
| | Lakshmi S Channavajjala | 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 and 8-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Receipt of amendment, remarks, terminal disclaimer and foreign priority all dated 12-15-03 is acknowledged.

Claims 1-6 and 8-10 are present for prosecution. Claim 7 has been canceled.

The following new rejection has been applied to instant claims:

Claim Rejections - 35 USC § 103

Claims 1-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,149,343 to Pauly in view of US 5,290,562 to Maybeck et al.

Pauly teach a topical cosmetic composition for promoting photo-pigmentation and photo-protection from UV rays comprising tyrosine in combination with amino acids such as tryptophan, histidine, lysine etc (abstract, col. 2, lines 47-66, col. 3, lines 3-33, examples 4-8) and pharmaceutically acceptable carrier. With respect to claim 4, the solubility of the amino acids (tryptophan, histidine and lysine) of Pauly is implicit although the reference does not specifically state the claimed solubility. With respect to claim 10, “a method of treating cosmetic substrate”, instant specification (page 44) states that the composition is applied to a substrate such as skin or hair. Pauly teaches applying the cosmetic composition dermatologically and hence reads on the instant substrate. Pauly does not teach tyrosine esters of the instant claims and instead teaches tyrosine and its complex salts by combining tyrosine with basic amino acids such as histidine.

Meybeck teaches cosmetic compositions containing methyl tyrosinate, ethyl tyrosinate or stearyl tyrosinate for increasing the content of melanin and thus improve the hair complexion.

Meybeck teaches that tyrosine being hydrophilic does not penetrate easily through the corneal layer and thus suggests using tyrosine esters such as methyl or ethyl tyrosinate and incorporated in liposomes (col. 2, lines 11-40 & lines 57-65). Thus, Maybeck teaches the composition containing tyrosinate salts for both skin melanogenesis as well as for improve the complexion or retard the graying of hair. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to substitute tyrosine of Pauly with the tyrosinate of Maybeck, in particular methyl tyrosinate that is also taught in the instant application examples, because Maybeck suggests tyrosinate esters unexpectedly make it possible to obtain a measurable increase in the amount of melanin and also exhibits better penetration than tyrosine. Therefore, a skilled artisan would have treated hair with the composition of Pauly containing amino acids such as histidine, lysine etc., in combination with tyrosinate esters of Maybeck with an expectation to increase the penetration of tyrosine across corneal layer, increase the melanin formation and thus increase the hair complexion.

Response to Arguments

Applicant's arguments filed 12-15-03 have been fully considered but they are not persuasive, in view of the new rejection:

It is to be noted that examiner has withdrawn the rejections of record and hence applicants' arguments regarding the teaching of Maybeck alone will be addressed:

Applicants argue that Meybeck offers no suggestion or motivation to substitute methyl or ethyl tyrosinate for tyrosine in the compositions of the other cited references. Applicants argue

that although Meybeck discloses compositions with methyl and ethyl tyrosinate, that clearly, the compositions of Meybeck target the skin or scalp to provide the disclosed benefit of increasing melanin formation in the skin. In contrast, Applicants argue that the hair care compositions of invention target the hair shaft, providing the benefit of improved strength and condition of the hair by the specific combination of amino acid compounds now claimed. Applicants also argue that the problem to be solved in Meybeck differs from the nature of the problem to be solved by Applicants' invention, which is directed to improve the strength and condition of the hair shaft and therefore as a result, there is no suggestion or motivation in Meybeck for one of ordinary skill in the art to substitute methyl or ethyl tyrosinate for tyrosine in Shiseido, Fischer, Ciavatta, or Gazanni. Therefore, applicants urge that currently amended claims are novel and nonobvious over the prior art of record.

Applicants arguments are not found persuasive because instant claims only state "hair care" in the preamble and does not recite any components in the claims that restrict the instant composition only for the use of hair and not skin. Besides, claim 10 recites "substrate", which is defined in the instant specification (page 44) as skin and hair. Further, in view of the new rejection, while Maybeck teaches for dermatological application (without the mention of hair), the newly applied rejection of Pauly states that tyrosine esters can be used for increasing melaogenesis or increased pigmentation in skin as well as hair and thus improve the hair condition or prevent graying of hair. Applicants' argument that instant composition is intended to improve and strengthen hair shaft is moot because applicants argue a limitation that is not claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
March 15, 2004